K080274

510(k) Summary of Safety and Effectiveness

APR 23 2008

Submitter Information:

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Device Name:

Trade Name: Ambulo 2400 Ambulatory Blood Pressure Monitoring System
Common Name: Ambulatory Blood Pressure Monitoring System
Classification Name: System, Measurement, Blood-Pressure, Non-Invasive
Classification Product code: DXN

Predicate Device(s):

The Ambulo 2400 is substantially equivalent to the A&D Medical model TM-2430 Ambulatory Blood Pressure Monitoring system cleared for marker under K992808.

Device Description:

The Ambulo 2400 is a compact, lightweight, non-invasive ambulatory blood monitoring system. The Ambulo 2400 can measure systolic and diastolic blood pressure, mean arterial pressure and pulse rate over a 24 hour period. It is easily configured and individually-fitted for each patient by a physician or health care professional. Measurements are automatically captured, without medical supervision, by the Ambulo 2400 and later downloaded to a computer for analysis and interpretation by a physician.

Since blood pressure naturally fluctuates throughout a full day according to various factors, such as sleep patterns, medication, diet, exercise and stress, a single measurement is not sufficient to make a sound diagnosis. Analyzing a person's blood pressure over an extended period of time can improve the diagnosis and ultimately the treatment. The Ambulo 2400 can collect blood pressure data under a variety of daily activities over a 24 hour period and then downloaded to a computer for analysis and treatment. The Ambulo 2400 may also be use on an ongoing basis to evaluate the effectiveness of a prescribed treatment.

Intended Use:

The Ambulo 2400 Ambulatory Blood Pressure Monitor is designed to measure systolic and diastolic blood pressure and pulse rate of adults who are eighteen (18) years and older, using the oscillometric method on a cuffed arm.

Technology Characteristics:

The Ambulo 2400 Ambulatory Blood Pressure Monitor is a battery-powered electromechanical device that utilizes a microcontroller along with air micropump and release valves to pump up and measure and store blood pressure and pulse rate via a standard cuff and using an oscillometric algorithm. The device is compact and lightweight, intended for everyday use by subjects (typically over a 24-hour period) to determine fluctuations in blood pressure during day and night. The device interfaces to a computer for configuration and download of measurements. The device has an LCD for displaying time of day, current status, measurement results, and/or any error conditions. The device also has a single button that allows the subject to initiate or stop a measurement, and to toggle the device between automatic measurement or PAUSE modes. The device is packaged with accessories including multiple cuffs, a carrying pouch, shoulder strap, application software, and a USB communication cable.

Summary of Performance Testing:

Standard	Title and Comments
EN/IEC60601-1	EN/IEC 60601 Medical Electrical Equipment - Part 1 General Requirements for Safety, 1988: Amendment 1, 1991, Amendment 2, 1995 **Note:** EN/IEC60601-1, UL2601-1, and CSA, No. 22.2 #601.1 M90 cover the same electrical safety requirements
EN/IEC60601-1-2:2001	EN/IEC 60601-1-2:2001 Medical Electrical Equipment - Collateral Standard; General Requirements for Safety: Electromagnetic Compatibility - Requirements and Test.
EN/IEC60601-1-4:1996	EN/IEC 60601-1-4:1996 Medical Electrical Equipment, - Collateral Standard – General Requirements for programmable electrical systems
EN/IEC 60601-1-6:2004	EN/IEC 60601-1-6:2004 Medical Electrical - Collateral standard; Usability
EN/IEC 60601-2-30:2000	EN/IEC 60601-2-30:2000 Medical Electrical Equipment – Part 2-30: Particular requirements for the safety including essential performance of automated cycling NIBP monitoring equipment

Standard	Title and Comments
AAMI/ANSI SP10;2002	AAMI/ANSI SP10;2002 manual, electronic or automated sphygmomanometers
EU 2002/95/EC	RoHS-compliance (Pb-free components and solder; mercury-free measurement device).
MIL – STD 810E, 1989	Temperature, Humidity, Altitude, Shock and Vibration
IEC 68-2-29	Operating Mechanical Bump Test
EN IEC 60601-1:2000	Operating Shock
ISTA Series 2 AB	Packaging Vibration

Conclusion:

The Ambulo 2400 Ambulatory Blood Pressure Monitoring System is as safe and effective as the predicate device when used according to the instructions in the User's Guide supplied with the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 23 2008

Tiba Medical, Inc.
c/o Mr. Merat Bagha
President
2701 NW Vaughn St., Suite 470
Portland, OR 97201

Re: K080274
Trade/Device Name: Ambulo™ 2400
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Monitoring System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: January 30, 2008
Received: February 1, 2008

Dear Mr. Bagha:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K080274

Device Name:
Ambulo 2400 Ambulatory Blood Pressure Monitoring System

Indication for use:
The Ambulo 2400 Ambulatory Blood Pressure Monitor is designed to measure systolic and diastolic blood pressure and pulse rate of adults who are eighteen (18) years and older, using the oscillometric method on a cuffed arm.

Prescription Use_____X_____ OR Over-The-Counter _____
(Per 21 CFR 801.109)

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K080274